

Quality Control Certificate



Borrelia + VisE IgG ELISA

REF RE57201	LOT EBV190	2026-07-31 YYYY-MM-DD
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Final Release Results:

	Conc. U/mL	Measured value OD	manual		e.g. automated/DSX
			Acceptable range* lower limit OD	upper limit OD	Measured value OD
CAL A	2	0.015	-	< 0.15	0.008
CAL B	10	0.295	0.10 (> CAL A)	0.55	0.262
CAL C	50	0.963	-	-	0.880
CAL D	200	1.993	> 1.20	-	1.989
CONTROL -	-	0.089	-	< 0.15	0.083
CONTROL +	-	1.713	> 1.00	-	1.678

*During automated procedure the optical densities of calibrators and controls may rise due to temperature and specific device conditions.
In case of none conformance with the OD ranges stated on the QC Certificate please contact IBL-International or use the validation criteria only!

Validation criteria (manual/automated)						
	Measured value		Acceptable range			
	Cut-off Index	Conc. U/mL	lower limit Cut-off Index	Conc. U/mL	upper limit Cut-off Index	Conc. U/mL
CONTROL -	0.3	4	-	-	<0.7	<8
CONTROL +	5.8	144	4.0	107	7.4	198

Kit Composition:

REF		LOT	
KEBV671A	CAL A	L536	2026-08
KEBV671B	CAL B	L536	2026-08
KEBV671C	CAL C	L536	2026-08
KEBV671D	CAL D	L536	2026-08
KEBV661	CONTROL -	L537	2026-08
KEBV651	CONTROL +	L538	2026-08
KEBV511	MTP	L530	2026-07
KEBV541	ENZCONJ	L539	2026-08
KEBV751	DILBUF	L493	2026-07
KIZZZ01	CONC WASHBUF	L459	2028-01
KEZZ991	TMB SUBS	M840-2	2027-02
KEZZ921	TMB STOP	M669	2026-07

All reagents of this kit containing human serum or plasma have been tested and were found negative for HIV I/II, HBsAg and HCV.

Valid edition of the instructions for use: 2024-11

This product has been tested successfully by the Quality Control Department and was released for sale according to the existing specifications.

Verified by: T. Borchert

Validation date: 2025-12-18

Accepted

This document has been produced electronically and is valid without a signature.